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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,175	07/14/2005	Peter Von Matt	TX/4-32732A	8299
75074 75074 7500 11/13/2008 NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC. 400 TECHNOLOGY SQUARE CAMBRIDGE, MA 02139			EXAMINER	
			KOSACK, JOSEPH R	
			ART UNIT	PAPER NUMBER
			1626	•
			MAIL DATE	DELIVERY MODE
			11/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/542,175 VON MATT ET AL. Office Action Summary Examiner Art Unit Joseph R. Kosack 1626 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 30 July 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-8.10 and 11 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-8,10 and 11 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Imformation Disclosure Statement(s) (PTC/S5/08)
Paper No(s)/Mail Date \_\_\_\_\_\_.

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

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### DETAILED ACTION

Claims 1-8 and 10-11 are pending in the instant application.

#### Amendments

The amendment filed on July 30, 2008 has been acknowledged and entered into the application file.

## Previous Claim Rejections - 35 USC § 103

Claims 1-8 and 10-11 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al. (WO 02/38561 A1).

Applicant has traversed the rejection on the grounds that it would not have been obvious to replace the quinoline or isoquinoline groups of Albert et al. with a pyridine group as in the instant application.

The Examiner understands the traversal asks for a document to show the change that is envisioned by one of ordinary skill in the art. The Examiner responds with Patani et al. (*Chem. Rev. 1996*, 3147-3176) which teaches that phenyl and pyridyl are bioisosteres of each other and that utilizing this tool in the pharmaceutical art would generate compounds with retention of biological activity. See page 3158, column 1. Additionally, even though a reference has not been provided to show that pyridine and its benzofused form, quinoline, are normally equivalent, Albert et al. teaches other systems of single rings and their benzofused form in this system with no loss of activity. Therefore, the bridge can be made from quinoline to pyridine as made by the Examiner in the instant case as Albert et al. also teaches the respective phenyl compounds. The rejection is maintained.

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## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skil in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 and 10-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al. (WO 02/38561 A1).

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The instant invention is drawn to compounds of the formula

 $k_a$  where: R is radical (a); R<sub>1</sub> is piperazine; and all other substituents are as defined. The instant invention is also drawn to its method of preparation and method of use.

### Determination of the scope and content of the prior art (MPEP §2141.01)

Albert et al. teach compounds of the formula where: A is

optionally substituted, Ra is H or optionally substituted C<sub>1-4</sub> alkyl, Rb is H or C<sub>1-4</sub> alkyl, R

is where G is CH, E is N, 
$$R_{11}$$
 is a heterocyclic residue, and  $R_{12}$  and  $R_{13}$  are optional substitutions. See pages 1-2. Albert et al. teaches specifically piperazine in the  $R_{11}$  substitution. One example is Example 163 on page 31. Albert et al. teaches the same process of forming the compounds. See page 6. Finally, Albert et al. teaches that the compounds are inhibitors of T lymphocytes and/or PKC. See pages 36.40

Ascertainment of the difference between the prior art and the claims (MPEP \$2141.02)

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Albert et al. teaches a quinoline (benzofused pyridine) and not teach a pyridine ring in the R position.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Albert et al. teaches other monocycles versus the benzofused cycles with no loss of utility and no apparent loss of activity. Specifically, Albert et al. teaches the R position to be phenyl or napthelene, and pyrimidine or quinazoline. See page 1.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to follow the synthetic scheme of Albert et al. and pyridine for quinoline to make the claimed invention with a reasonable expectation of success. The motivation to do so is provided by Albert et al. Albert et al. teach the use of the synthesized compounds to treat various diseases mediated by T lymphocytes and/or PKC and the substitution for benzofused rings for the corresponding monocycles. See page 1 and 36-40.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

#### Conclusion

Claims 1-8 and 10-11 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Joseph R Kosack/ Examiner, Art Unit 1626

/REI-TSANG SHIAO / Primary Examiner, Art Unit 1626